IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NATERA, INC.,	)	
Plaintiff / Counterclaim-Defendant,	)	
v.	)	C.A. No. 20-125-LPS
ARCHERDX, INC.,	)	**DEMAND FOR JURY TRIAL**
Defendant / Counterclaimant.	)	

DEFENDANT ARCHERDX, INC.'S ANSWER AND COUNTERCLAIMS TO PLAINTIFF'S COMPLAINT FOR PATENT INFRINGEMENT

Defendant ArcherDX, Inc. ("ArcherDX" or "Defendant") hereby submits the following preliminary statement, answer, defenses (affirmative and otherwise), and counterclaims to Natera, Inc.'s ("Natera" or "Plaintiff") Complaint (D.I. 1) filed on January 27, 2020.

PRELIMINARY STATEMENT

a. ArcherDX is a leading genomics company democratizing precision oncology, including the use of genetic information from genomic tumor profiling to guide cancer therapy optimization and monitoring. ArcherDX offers a suite of innovative products and services that are highly accurate, personal, actionable, and easy to use in local settings.

b. With its proprietary product development platform, ArcherDX is working to develop industry-leading products and services to optimize therapy and monitor cancer. Specifically, ArcherDX is in the process of developing *in vitro* diagnostic ("IVD") products for approval or clearance by the United States Food and Drug Administration ("FDA"). For example, STRATAFIDE™ is in development as a universal IVD and companion diagnostic product. STRATAFIDE™ has received Breakthrough Device designation from the FDA. In January 2020, ArcherDX also received Breakthrough Device designation from the FDA for its

Personalized Cancer Monitoring product, PCM, which it is developing as an IVD to non-invasively and quantitatively measure cancer recurrence or progression, as well as therapeutic efficacy.

c. Asserted U.S. Patent No. 10,538,814 ("the '814 Patent") is the result of a protracted and convoluted prosecution at the United States Patent and Trademark Office ("USPTO"). Over the course of a decade, Natera filed 16 provisional patent applications, 10 continuation or continuation-in-part applications, and it abandoned almost half of those applications. In connection with those applications, Natera filed *hundreds* of proposed claims with the USPTO and disclosed *thousands* of references. But Natera did not disclose key prior art that discloses or renders obvious the claimed methods for amplifying and sequencing cell-free DNA.

d. Moreover, despite this protracted and convoluted prosecution history, prior to April 30, 2019, when it filed the application that resulted in the '814 Patent, Natera had *never* disclosed nor sought to patent the methods recited in the claims of the '814 Patent. Indeed, that is because Natera did not invent those methods and, upon information and belief, Natera itself does not even practice the methods claimed in the '814 Patent.

e. Instead, on information and belief, Natera is a copyist that drafted claims designed to cover ArcherDX's proprietary Anchored Multiplex PCR ("AMP™") processes—after being outcompeted in the marketplace; ArcherDX's proprietary AMP™ processes are technologically and commercially superior to Natera's legacy technology.

f. Notably, Natera filed the application leading to the '814 Patent shortly after it gained access to confidential information relating to ArcherDX's products, including LIQUIDPlex™, STRATAFIDE™ and PCM.

g. As described below, Natera's efforts violate the patent laws on multiple levels: the belatedly drafted claims fail to satisfy the substantive requirements of patentability, including 35 U.S.C. §§ 101, 102, 103, and/or 112; no one associated with Natera invented the claimed methods; and Natera's unreasonable delay in prosecution—coupled with its filing of the application leading to the '814 Patent soon after it gained access to ArcherDX's confidential information and for the purpose of attempting to unjustifiably regain traction in the marketplace—triggers the doctrines of unclean hands and prosecution laches, barring Natera's infringement claims.

h. In any event, Natera is a poor copyist. ArcherDX does not practice the technology claimed in the '814 Patent, and therefore does not infringe. Moreover, activities complained of by Natera are protected by the safe harbor of 35 U.S.C. § 271(e)(1) and, accordingly, immune from infringement claims.

i. Finally, in an attempt to harass and cast a cloud over ArcherDX, Natera improperly seeks a preliminary and inappropriate advisory opinion from the Court regarding ArcherDX's STRATAFIDE™ and PCM products, which are still in the development stage.

j. In sum, Natera's meritless Complaint represents a last-ditch effort to bully a smaller, fast-growing competitor using the courtroom, because Natera cannot compete with its technically inferior products in the marketplace.

ANSWER

ArcherDX denies all allegations in the Complaint, whether express or implied, that are not specifically admitted below, including all allegations in any headings or unnumbered paragraphs. ArcherDX further denies that Natera is entitled to the requested relief or any other relief.

OVERVIEW OF THE ACTION[1]

1. ArcherDX expressly denies that any ArcherDX product falls within the alleged scope of any claim of the '814 Patent, and that any of its activities constitute "infringement of Natera's innovative, patented technology." ArcherDX admits that the Complaint purports to state an action for infringement of the '814 Patent. ArcherDX admits that LIQUIDPlex™ was previously called Reveal ctDNA. LIQUIDPlex™ is a product for research use only, and it uses ArcherDX's proprietary AMP™ chemistry. ArcherDX further admits that it is currently developing its STRATAFIDE™ and PCM products for approval or clearance by the FDA. ArcherDX further denies each and every allegation of paragraph 1 of the Complaint.

THE PARTIES

2. ArcherDX is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 2 of the Complaint, and therefore denies each and every allegation in that paragraph.

3. Paragraph 3 of the Complaint contains statements of opinion to which no response is required. To the extent paragraph 3 contains factual allegations, ArcherDX is without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore denies each and every allegation in that paragraph.

4. Paragraph 4 of the Complaint contains statements of opinion to which no response is required. To the extent paragraph 4 contains factual allegations, ArcherDX is without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore denies each and every allegation in that paragraph.

[1] For the Court's convenience, ArcherDX generally adopts the headings used in Natera's Complaint. In so doing, ArcherDX does not admit that the headings are accurate, and ArcherDX reserves the right to contest any statements or characterizations set forth under them. To the extent the headings constitute allegations requiring a response, they are denied.

5. Paragraph 5 of the Complaint contains statements of opinion to which no response is required. To the extent paragraph 5 contains factual allegations, ArcherDX is without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore denies each and every allegation in that paragraph.

6. Paragraph 6 of the Complaint contains statements of opinion to which no response is required. To the extent paragraph 6 contains factual allegations, ArcherDX is without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore denies each and every allegation in that paragraph.

7. Paragraph 7 of the Complaint contains statements of opinion to which no response is required. To the extent paragraph 7 contains factual allegations, ArcherDX is without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore denies each and every allegation in that paragraph.

8. Paragraph 8 of the Complaint contains statements of opinion to which no response is required. To the extent paragraph 8 contains factual allegations, ArcherDX is without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore denies each and every allegation in that paragraph.

9. ArcherDX denies the allegations of paragraph 9 of the Complaint. ArcherDX specifically denies that ArcherDX has committed the alleged acts of infringement and further denies that the ’814 Patent claims an “invention.” ArcherDX avers that the ’814 Patent is invalid for failure to satisfy one or more conditions for patentability set forth under 35 U.S.C. including but not limited to §§ 101, 102, 103, and 112 *et seq*.; no one associated with Natera invented the claimed methods; and the ’814 Patent is unenforceable against ArcherDX by reason of Natera’s unclean hands and prosecution laches.

10. ArcherDX admits that it is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 2477 55th Street, Suite 202, Boulder, Colorado 80301.

11. ArcherDX denies the allegations of paragraph 11 of the Complaint. ArcherDX developed its own proprietary AMP™ chemistry, technology platform, and applications, which are covered by three issued patents and 15 pending patent applications in the United States and two issued patents and 43 pending patent applications in foreign countries.

JURISDICTION AND VENUE

12. The allegation of jurisdiction in paragraph 12 of the Complaint constitutes a legal conclusion that requires no response. To the extent a response is required, ArcherDX admits that the Complaint purports to state an action that arises under the patent laws of the United States, 35 U.S.C. § 1, *et seq*., 28 U.S.C. §§ 1331 and 1338(a), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. ArcherDX specifically denies that the Complaint states a claim upon which relief may be granted. ArcherDX further denies that the Complaint pleads the existence of an "actual controversy" between the parties under the Declaratory Judgment Act with respect to the yet to be FDA approved sale of ArcherDX's IVD products. Except as expressly admitted herein, ArcherDX denies each and every allegation of paragraph 12.

13. The allegation of jurisdiction in paragraph 13 of the Complaint constitutes a legal conclusion that requires no response. To the extent a response is required, ArcherDX does not contest that this Court has personal jurisdiction over ArcherDX for purposes of this action. ArcherDX admits that it is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 2477 55th Street, Suite 202, Boulder, Colorado 80301. Except as expressly admitted herein, ArcherDX denies each and every allegation of paragraph 13.

14. The allegation of jurisdiction in paragraph 14 of the Complaint constitutes a legal conclusion that requires no response. To the extent a response is required, ArcherDX does not contest that this Court has personal jurisdiction over ArcherDX for purposes of this action. ArcherDX specifically denies that ArcherDX has committed the alleged acts of infringement in this District or anywhere else. Except as expressly admitted herein, ArcherDX denies each and every allegation of paragraph 14.

15. The allegation of jurisdiction in paragraph 15 of the Complaint constitutes a legal conclusion that requires no response. To the extent a response is required, ArcherDX does not contest that this Court has personal jurisdiction over ArcherDX for purposes of this action. ArcherDX admits that it has initiated a civil action in *ArcherDX, Inc. et al v. Qiagen Sciences, LLC et al,* 18-1019-MN (D. Del. 2018). Except as expressly admitted herein, ArcherDX denies each and every allegation of paragraph 15.

16. The allegation of venue in paragraph 16 of the Complaint constitutes a legal conclusion that requires no response. To the extent a response is required, ArcherDX does not contest that, for the purposes of this action, and without waiving any defense of improper venue in connection with any other cause of action or claim, venue properly lies in this judicial district pursuant to 28 U.S.C. § 1400(b). ArcherDX admits that it is a Delaware corporation. Except as expressly admitted herein, ArcherDX further denies each and every allegation of paragraph 16.

BACKGROUND

17. Paragraph 17 of the Complaint contains statements of opinion to which no response is required. To the extent paragraph 17 contains factual allegations, ArcherDX is without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore denies each and every allegation in that paragraph.

18. Paragraph 18 of the Complaint contains statements of opinion to which no response is required. To the extent paragraph 18 contains factual allegations, ArcherDX is without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore denies each and every allegation in that paragraph.

19. Paragraph 19 of the Complaint contains statements of opinion to which no response is required. To the extent paragraph 19 contains factual allegations, ArcherDX is without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore denies each and every allegation in that paragraph.

20. Paragraph 20 of the Complaint contains statements of opinion to which no response is required. To the extent paragraph 20 contains factual allegations, ArcherDX is without knowledge or information sufficient to form a belief as to the truth of the allegations, and therefore denies each and every allegation in that paragraph.

21. Paragraph 21 of the Complaint contains statements of opinion to which no response is required. To the extent paragraph 21 contains factual allegations, Natera does not identify any particular "MRD assessment" in paragraph 21, and accordingly ArcherDX is without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore denies each and every allegation in that paragraph.

22. Paragraph 22 of the Complaint contains statements of opinion to which no response is required. To the extent paragraph 22 contains factual allegations, ArcherDX is without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore denies each and every allegation in that paragraph.

23. Paragraph 23 of the Complaint contains statements of opinion to which no response is required. To the extent paragraph 23 contains factual allegations, ArcherDX is

without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore denies each and every allegation in that paragraph.

24. Paragraph 24 of the Complaint contains statements of opinion to which no response is required. To the extent paragraph 24 contains factual allegations, ArcherDX is without knowledge or information sufficient to form a belief as to the truth of the allegations, and therefore denies each and every allegation in that paragraph.

25. Paragraph 25 of the Complaint contains statements of opinion to which no response is required. To the extent paragraph 25 contains factual allegations, ArcherDX is without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore denies each and every allegation in that paragraph.

26. ArcherDX denies that the '814 Patent relates to "innovative new methods for amplifying and sequencing cell-free DNA." ArcherDX further denies that the claims of the '814 Patent recite methods that are novel or innovative. ArcherDX avers that the '814 Patent is invalid for failure to satisfy one or more conditions for patentability set forth under 35 U.S.C. including but not limited to §§ 101, 102, 103, and 112 *et seq.*; no one associated with Natera invented the claimed methods; and the '814 Patent is unenforceable against ArcherDX by reason of Natera's unclean hands and prosecution laches. Except as expressly denied herein, ArcherDX is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 26 of the Complaint, and therefore denies each and every allegation in that paragraph.

GENERAL BACKGROUND OF THE '814 PATENT

27. ArcherDX admits that a document purporting to be a copy of the '814 Patent is attached to the Complaint as Exhibit 1. ArcherDX admits that, on its face, the '814 Patent, titled "Methods for Simultaneous Amplification of Target Loci," indicates that it was issued by the

USPTO on January 21, 2020. As to the remaining allegations, ArcherDX is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 27 of the Complaint, and therefore denies each and every allegation of that paragraph.

28. ArcherDX admits that claim 1 of the '814 Patent recites:

> A method for amplifying and sequencing DNA, comprising:
> ligating adaptors to cell-free DNA isolated from a biological sample, wherein the adaptors each comprises a universal priming site;
> performing a first PCR to simultaneously amplify at least 10 target loci using a universal primer and at least 10 target-specific primers in a single reaction volume;
> performing a second, nested PCR to simultaneously amplify the at least 10 target loci using the universal primer and at least 10 inner target-specific primers in a single reaction volume, wherein at least one of the primers comprises a sequencing tag;
> performing high-throughput sequencing to sequence the amplified DNA comprising the target loci.

ArcherDX admits that claim 1 recites "a method for amplifying and sequencing DNA" and further recites "PCR" and "high-throughput sequencing." Except as expressly admitted herein, ArcherDX denies each and every allegation of paragraph 28 of the Complaint.

29. Paragraph 29 of the Complaint contains statements of opinion and legal conclusions to which no response is required. To the extent a response is required, ArcherDX denies each and every allegation in that paragraph. Indeed, as set forth in ArcherDX's Counterclaims, Natera's own admissions made in court filings in this District and elsewhere contradict the allegations of paragraph 29 of the Complaint.

30. Paragraph 30 of the Complaint contains statements of opinion and legal conclusions to which no response is required. To the extent a response is required, ArcherDX denies each and every allegation in that paragraph. Indeed, as set forth in ArcherDX's Counterclaims, Natera's own admissions made in court filings in this District and elsewhere contradict the allegations of paragraph 30 of the Complaint.

31. ArcherDX admits the language appearing in the block quote in paragraph 31 of the Complaint reflects a statement made by the USPTO examiner during the prosecution of the '814 Patent. ArcherDX denies the allegation that "the USPTO examiner found the claims to be non-routine and non-conventional." Indeed, as set forth in ArcherDX's Counterclaims, Natera's own admissions made in court filings in this District and elsewhere contradict the allegations of paragraph 31. Moreover, ArcherDX avers that, contrary to the USPTO examiner's statement, "amplification of . . . circulating nucleic acids" is disclosed in the prior art, including in U.S. Patent App. Pub. No. 2010/0120038 ("Mir"). Archer further avers that "sequencing steps, . . . incorporat[ing] a universal or common primer, and . . . a sequencing tag" are also disclosed in the prior art, including in Mir. Natera disclosed Mir as one of *thousands* of references disclosed during prosecution of the '814 Patent.

ARCHER'S ALLEGED INFRINGING ACTIVITIES

32. ArcherDX admits that LIQUIDPlex™ utilizes ArcherDX's proprietary AMP™ technology to preferentially enrich highly fragmented ctDNA over genomic DNA and has application for solid tumors as well as hematological malignancies. LIQUIDPlex™ is a product available for research use only. ArcherDX further admits that it is currently developing STRATAFIDE™ and PCM for FDA approval or clearance. Except as expressly admitted herein, ArcherDX denies each and every allegation of paragraph 32 of the Complaint.

33. ArcherDX admits that a document purporting to be a claim chart, and documents cited in the claim chart, are attached to the Complaint as Exhibit 2 and Exhibits 3-11. The claim chart contains statements of opinion and legal conclusions to which no response is required. To the extent a response is required, ArcherDX specifically denies each and every allegation in the claim chart, and further denies that Exhibits 3-11 support the allegations, opinions, and legal

conclusions in the claim chart. Except as expressly admitted herein, ArcherDX denies each and every allegation of paragraph 33 of the Complaint.

34. Exhibit 2 contains statements of opinion and legal conclusions to which no response is required. To the extent a response is required, ArcherDX denies each and every allegation in Exhibit 2. ArcherDX further denies each and every allegation of paragraph 34 of the Complaint.

35. ArcherDX admits that LIQUIDPlex™ applies ArcherDX's proprietary AMP™ technology to preferentially enrich highly fragmented ctDNA over genomic DNA. Except as expressly admitted herein, ArcherDX denies each and every allegation of paragraph 35 of the Complaint.

36. ArcherDX admits that STRATAFIDE™ is its product and is currently being developed for FDA approval or clearance. Except as expressly admitted herein, ArcherDX denies each and every allegation of paragraph 36 of the Complaint.

37. ArcherDX admits that PCM is its product and is currently being developed for FDA approval or clearance. Except as expressly admitted herein, ArcherDX denies each and every allegation of paragraph 37 of the Complaint.

38. The allegations of paragraph 38 of the Complaint constitute legal conclusions that require no response. To the extent a response is deemed required, ArcherDX denies each and every allegation in that paragraph.

39. The allegations of paragraph 39 of the Complaint constitute legal conclusions that require no response. To the extent a response is deemed required, ArcherDX denies each and every allegation in that paragraph.

40. The allegations of paragraph 40 of the Complaint constitute legal conclusions that require no response. To the extent a response is deemed required, ArcherDX denies each and every allegation in that paragraph.

41. The allegations of paragraph 41 of the Complaint constitute legal conclusions that require no response. To the extent a response is deemed required, ArcherDX denies each and every allegation in that paragraph.

42. The allegations of paragraph 42 of the Complaint constitute legal conclusions that require no response. To the extent a response is deemed required, ArcherDX denies each and every allegation in that paragraph.

43. The allegations of paragraph 43 of the Complaint constitute legal conclusions that require no response. To the extent a response is deemed required, ArcherDX denies each and every allegation in that paragraph.

44. The allegations of paragraph 44 of the Complaint constitute legal conclusions that require no response. To the extent a response is deemed required, ArcherDX denies each and every allegation in that paragraph.

45. The allegations of paragraph 45 of the Complaint constitute legal conclusions that require no response. To the extent a response is deemed required, ArcherDX denies each and every allegation in that paragraph.

46. The allegations of paragraph 46 of the Complaint constitute legal conclusions that require no response. To the extent a response is deemed required, ArcherDX denies each and every allegation in that paragraph.

47. The allegations of paragraph 47 of the Complaint constitute legal conclusions that require no response. To the extent a response is deemed required, ArcherDX denies each and every allegation in that paragraph.

48. The allegations of paragraph 48 of the Complaint constitute legal conclusions that require no response. To the extent a response is deemed required, ArcherDX denies each and every allegation in that paragraph.

49. The allegations of paragraph 49 of the Complaint constitute legal conclusions that require no response. To the extent a response is deemed required, ArcherDX denies each and every allegation in that paragraph.

50. The allegations of paragraph 50 of the Complaint constitute legal conclusions that require no response. To the extent a response is deemed required, ArcherDX denies each and every allegation in that paragraph.

51. The allegations of paragraph 51 of the Complaint constitute legal conclusions that require no response. To the extent a response is deemed required, ArcherDX denies each and every allegation in that paragraph.

52. The allegations of paragraph 52 of the Complaint constitute legal conclusions that require no response. To the extent a response is deemed required, ArcherDX denies each and every allegation in that paragraph.

53. The allegations of paragraph 53 of the Complaint constitute legal conclusions that require no response. To the extent a response is deemed required, ArcherDX denies each and every allegation in that paragraph.

54. The allegations of paragraph 54 of the Complaint constitute legal conclusions that require no response. To the extent a response is deemed required, ArcherDX denies each and every allegation in that paragraph.

55. The allegations of paragraph 55 of the Complaint constitute legal conclusions that require no response. To the extent a response is deemed required, ArcherDX denies each and every allegation in that paragraph.

56. The allegations of paragraph 56 of the Complaint constitute legal conclusions that require no response. To the extent a response is deemed required, ArcherDX denies each and every allegation in that paragraph.

57. The allegations of paragraph 57 of the Complaint constitute legal conclusions that require no response. To the extent a response is deemed required, ArcherDX denies each and every allegation in that paragraph.

58. The allegations of paragraph 58 of the Complaint constitute legal conclusions that require no response. To the extent a response is deemed required, ArcherDX denies each and every allegation in that paragraph.

59. The allegations of paragraph 59 of the Complaint constitute legal conclusions that require no response. To the extent a response is deemed required, ArcherDX denies each and every allegation in that paragraph.

60. The allegations of paragraph 60 of the Complaint constitute legal conclusions that require no response. To the extent a response is deemed required, ArcherDX denies each and every allegation in that paragraph.

61. The allegations of paragraph 61 of the Complaint constitute legal conclusions that require no response. To the extent a response is deemed required, ArcherDX denies each and every allegation in that paragraph.

62. The allegations of paragraph 62 of the Complaint constitute legal conclusions that require no response. To the extent a response is deemed required, ArcherDX denies each and every allegation in that paragraph.

63. The allegations of paragraph 63 of the Complaint constitute legal conclusions that require no response. To the extent a response is deemed required, ArcherDX denies each and every allegation in that paragraph.

64. ArcherDX admits that LIQUIDPlex™ is a product available for research use only, and not for the diagnosis or treatment of disease. Except as expressly admitted herein, ArcherDX denies each and every allegation of paragraph 64 of the Complaint.

65. ArcherDX denies that it has sought or received from the FDA Breakthrough Device Designation for LIQUIDPlex™. ArcherDX admits that LIQUIDPlex™ is a product available for research use only, and not for the diagnosis or treatment of disease. Natera's allegation that "Archer intends to sell the product for non-research purposes immediately upon approval" is baseless and fails to give rise to an "actual controversy" between the parties under the Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq*. In particular, Natera fails to identify a concrete and particularized, and actual or imminent, injury-in-fact that is sufficient to warrant the issuance of a declaratory judgment. Except as expressly admitted herein, ArcherDX denies each and every allegation of paragraph 65 of the Complaint.

66. ArcherDX admits that it received the FDA's Breakthrough Device Designation for STRATAFIDE™ in December 2018. Natera's allegation that "Archer intends to sell the

product immediately upon approval" fails to give rise to an "actual controversy" between the parties under the Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq*. In particular, Natera fails to identify a concrete and particularized, and actual or imminent, injury-in-fact that is sufficient to warrant the issuance of a declaratory judgment. Except as expressly admitted herein, ArcherDX denies each and every allegation of paragraph 66 of the Complaint.

67. ArcherDX admits that it received the FDA's Breakthrough Device Designation for PCM in January 2020. Natera's allegation of "Archer intends to sell the product immediately upon approval" fails to give rise to an "actual controversy" between the parties under the Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq*. In particular, Natera fails to identify a concrete and particularized, and actual or imminent, injury-in-fact that is sufficient to warrant the issuance of a declaratory judgment. Except as expressly admitted herein, ArcherDX denies each and every allegation of paragraph 67 of the Complaint.

68. ArcherDX admits that it operates a CLIA-certified laboratory. Except as expressly admitted herein, ArcherDX denies each and every allegation of paragraph 68 of the Complaint.

69. The allegations of paragraph 69 of the Complaint constitute legal conclusions that require no response. To the extent a response is deemed required, ArcherDX specifically denies that it has or has had the requisite intent or knowledge to induce or contribute to the direct infringement of the '814 Patent by another. Except as expressly admitted herein, ArcherDX denies each and every allegation of paragraph 69 of the Complaint.

70. The allegations of paragraph 70 of the Complaint constitute legal conclusions that require no response. To the extent a response is deemed required, ArcherDX specifically denies that it has or has had the requisite intent or knowledge to induce or contribute to the direct

infringement of the '814 Patent by another. Further, Natera's allegation that "Stratafide will be sold as a kit or as component parts…" fails to give rise to an "actual controversy" between the parties under the Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq*. In particular, Natera fails to identify a concrete and particularized, and actual or imminent, injury-in-fact that is sufficient to warrant the issuance of a declaratory judgment. ArcherDX denies each and every other allegation of paragraph 70 of the Complaint.

71. The allegations of paragraph 71 of the Complaint constitute legal conclusions that require no response. To the extent a response is deemed required, ArcherDX specifically denies that it has or has had the requisite intent or knowledge to induce or contribute to the direct infringement of the '814 Patent by another. Further, Natera's allegation that "PCM will be sold as a kit or as component parts…" fails to give rise to an "actual controversy" between the parties under the Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq*. In particular, Natera fails to identify a concrete and particularized, and actual or imminent, injury-in-fact that is sufficient to warrant the issuance of a declaratory judgment. ArcherDX denies each and every other allegation of paragraph 71 of the Complaint.

72. ArcherDX denies each and every allegation of paragraph 72 of the Complaint. ArcherDX avers that it developed its own proprietary AMP™ chemistry, technology platform, and applications.

73. To the extent that paragraph 73 excerpts the contents of an ArcherDX document, the document speaks for itself. ArcherDX avers that the TRACERx investigators, led by Professor Charles Swanton, Group Leader, University College London ("UCL") and the Francis Crick Institute, and Dr. Christopher Abbosh, Principal Clinical Fellow, UCL, are utilizing ArcherDX's technology—and not Natera's inferior technology—to detect low-volume minimal

residual disease at high levels of sensitivity to help achieve TRACERx's goal of a more personalized approach to developing cancer treatments. Paragraph 73 of the Complaint further contains legal conclusions that require no response. To the extent paragraph 73 contains factual allegations, ArcherDX is without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore denies each and every allegation in that paragraph.

74. ArcherDX denies each and every allegation of paragraph 74 of the Complaint. ArcherDX avers that it developed its own proprietary AMP™ chemistry, technology platform, and applications.

75. ArcherDX admits that it is a direct competitor of Natera in the development of IVD products. Except as expressly admitted herein, ArcherDX denies each and every allegation of paragraph 75 of the Complaint.

76. ArcherDX admits that it gained knowledge of the '814 Patent after it received a copy of the Complaint. Except as expressly admitted herein, ArcherDX denies each and every allegation of paragraph 76 of the Complaint.

RESPONSE TO COUNT I: ALLEGED INFRINGEMENT OF THE '814 PATENT

77. ArcherDX restates and incorporates by reference, its preliminary statement, and each and every response set forth above in paragraphs 1-76 of its Answer, as if fully set forth herein.

78. ArcherDX is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 78 of the Complaint, and therefore denies each and every allegation in that paragraph.

79. ArcherDX denies each and every allegation of paragraph 79 of the Complaint. In addition, the Complaint, in whole or in part, fails to state a claim upon which relief may be granted. For example, the Complaint does not allege that ArcherDX has engaged in any

activities with respect to STRATAFIDE™ or PCM that fall outside the safe harbor provided by 35 U.S.C. § 271(e)(1).

80. ArcherDX denies each and every allegation of paragraph 80 of the Complaint. In addition, the Complaint, in whole or in part, fails to state a claim upon which relief may be granted. For example, the Complaint does not allege that ArcherDX has engaged in any activities with respect to STRATAFIDE™ or PCM that fall outside the safe harbor provided by 35 U.S.C. § 271(e)(1).

81. ArcherDX denies each and every allegation of paragraph 81 of the Complaint. In addition, the Complaint, in whole or in part, fails to state a claim upon which relief may be granted. For example, the Complaint does not allege that ArcherDX has engaged in any activities with respect to STRATAFIDE™ or PCM that fall outside the safe harbor provided by 35 U.S.C. § 271(e)(1).

82. ArcherDX denies each and every allegation of paragraph 82 of the Complaint.

83. ArcherDX denies each and every allegation of paragraph 83 of the Complaint.

RESPONSE TO COUNT II: REQUEST FOR DECLARATORY JUDGMENT RELATING TO ALLEGED FUTURE INFRINGEMENT OF THE '814 PATENT

84. ArcherDX restates and incorporates by reference, its preliminary statement, and each and every response set forth above in paragraphs 1-83 of its Answer, as if fully set forth herein.

85. ArcherDX admits that it has received the FDA's Breakthrough Device Designation for STRATAFIDE™ and PCM. ArcherDX denies that it has sought or received, or presently intends to seek, Breakthrough Device Designation for LIQUIDPlex™ from the FDA. Natera's allegation that "Archer intends to engage in the commercial manufacture, use, offer for sale, and sale of the Accused Products if and when it receives FDA approval to do so" fails to

give rise to an "actual controversy" between the parties under the Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq*. In particular, Natera fails to identify a concrete and particularized, and actual or imminent, injury-in-fact that is sufficient to warrant the issuance of a declaratory judgment. Except as expressly admitted herein, ArcherDX denies each and every allegation of paragraph 85 of the Complaint.

86. ArcherDX denies each and every allegation of paragraph 86 of the Complaint.

87. ArcherDX denies each and every allegation of paragraph 87 of the Complaint.

88. ArcherDX denies each and every allegation of paragraph 88 of the Complaint.

89. ArcherDX denies each and every allegation of paragraph 89 of the Complaint.

RESPONSE TO NATERA'S PRAYER FOR RELIEF

90. ArcherDX denies that Natera is entitled to any relief from ArcherDX, including the relief Natera seeks in Paragraphs (A) – (F) of its Prayer for Relief. Natera's Prayer for Relief should be denied in its entirety and with prejudice, and Natera should be awarded nothing. ArcherDX further denies each and every allegation in Natera's Prayer for Relief.

ARCHERDX'S DEFENSES

91. ArcherDX alleges and asserts the following defenses in response to the allegations in the Complaint, undertaking the burden of proof only as to those defenses deemed affirmative defenses by law, regardless of how such defenses are denominated herein. ArcherDX reserves the right to amend its Answer, including to modify, amend, and/or expand upon its defenses once discovery progresses. Without conceding that any of the following defenses must necessarily be pled, or that any of the following defenses is not already at issue by virtue of the foregoing denials, and without reducing or removing Natera's burdens of proof on its affirmative claims against ArcherDX, ArcherDX alleges and asserts as follows:

FIRST DEFENSE
(Failure to State a Claim)

92. The allegations and claims in the Complaint, in whole or in part, fail to state a claim upon which relief may be granted.

93. For example, the Complaint does not allege that ArcherDX has engaged in any activities with respect to STRATAFIDE™ or PCM that fall outside the safe harbor provided by 35 U.S.C. § 271(e)(1).

94. The Complaint further fails to state a claim upon which relief may be granted because, as set forth in ArcherDX's Counterclaims, the claims of the '814 Patent are invalid under one or more of 35 U.S.C. § 101, 102, 103, 112, *et seq*.

SECOND DEFENSE
(Lack of Subject Matter Jurisdiction)

95. There is no subject matter jurisdiction because the Complaint fails to plead an "actual controversy" between the parties under the Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq*., with respect to ArcherDX's IVD products.

96. None of LIQUIDPlex™, STRATAFIDE™ and PCM are presently cleared or approved by the FDA. ArcherDX has not sought or received, nor does it presently intend to seek, Breakthrough Device Designation for LIQUIDPlex™ from the FDA. Both STRATAFIDE™ and PCM require premarket approval or approval or clearance pursuant to 21 U.S.C. § 360(k) ("510k approval or clearance") to be sold commercially. ArcherDX has not submitted an application for FDA clearance or approval to the FDA for either STRATAFIDE™ or PCM.

97. The development of the data necessary to obtain regulatory clearance and/or approval of STRATAFIDE™ and PCM is ongoing, but is time-consuming and carries with it the

risk of not yielding the desired results. Ultimately, ArcherDX may not be able to obtain FDA clearance or approval of STRATAFIDE™ or PCM.

THIRD DEFENSE
(Non-Infringement)

98. ArcherDX has not infringed, and is not infringing, literally or under the doctrine of equivalents, directly, or jointly, any valid and enforceable claim of the '814 Patent.

99. For example, claim 1 of the '814 Patent recites "performing a first PCR…using a universal primer" and "performing a second, nested PCR…using the universal primer." ArcherDX's accused AMP™ process does not include "a second, nested PCR…using the universal primer" of the first PCR.

100. Further, ArcherDX has not infringed contributorily or by inducement any valid and enforceable claim of the '814 Patent because there is no direct infringement; ArcherDX's accused AMP™ processes do not fall within the claims of the '814 Patent. Moreover, to the extent Natera asserts that ArcherDX indirectly infringes the '814 Patent, including by inducement of infringement, ArcherDX is not liable because, at a minimum, ArcherDX lacks the requisite intent or knowledge to induce direct infringement of the '814 Patent by another. ArcherDX also lacks the knowledge required for a finding of contributory infringement under 35 U.S.C. § 271(c).

FOURTH DEFENSE
(Safe Harbor)

101. Natera's patent infringement claims are barred in whole or in part because the alleged infringing activities fall within the safe harbor provision of 35 U.S.C. § 271(e)(1).

102. STRATAFIDE™ and PCM are in development for approval or clearance by the FDA.

103. Neither STRATAFIDE™ nor PCM is presently cleared or approved by the FDA. Both STRATAFIDE™ and PCM require premarket approval or 510(k) approval or clearance to be sold commercially.

FIFTH DEFENSE
(Invalidity)

104. Each of the asserted claims of the '814 Patent are invalid for failure to satisfy one or more conditions for patentability set forth under 35 U.S.C. including but not limited to §§ 101, 102, 103, and 112 *et seq.*, and the rules, regulations, and laws pertaining to those provisions, including the applicable provisions of Title 37 of the Code of Federal Regulations. The '814 Patent is invalid under 35 U.S.C. §§ 102 and/or § 103 in view of Mir, alone or in combination with additional prior art, including Diego Spertini, *Screening of Transgenic Plants by Amplification of Unknown Genomic DNA Flanking T-DNA*, 27 BioTechniques 308 (1999) ("Spertini") or U.S. Patent App. No. 2007/0031857 ("Makarov"), which disclose all elements of the '814 Patent. Natera disclosed Mir as one of *thousands* of references during prosecution of the '814 Patent. Natera did not disclose either Spertini or Makarov to the USPTO during prosecution of the '814 Patent. Moreover, the '814 Patent is at least obvious under 35 U.S.C. § 103 given Natera's own admissions made in court filings in this District and elsewhere, which are delineated below in ArcherDX's Counterclaims.

105. The '814 Patent is also not entitled to a priority date earlier than its filing date of April 30, 2019, because Natera's provisional applications and earlier-filed applications do not comply with the requirements of 35 U.S.C § 112, as required by 35 U.S.C §§ 119 and 120.

106. The provisional applications and earlier-filed applications do not contain a written description of the claims of the '814 Patent or contain sufficient information to enable a person

of ordinary skill in the art to which they pertain to practice the full scope of the claims of the ’814 Patent.

107. Indeed, none of the provisional applications or earlier-filed applications disclosed or sought claims corresponding to the claims of the ’814 Patent, which recite processes that Natera did not invent.

SIXTH DEFENSE
(Prosecution History Estoppel/Disclaimer)

108. Natera is estopped from construing the claims of the ’814 Patent to cover or include, either literally or by application of the doctrine of equivalents, products manufactured, used, imported, sold, or offered for sale by ArcherDX or methods used by ArcherDX because of amendments, admissions, representations, or statements made before the USPTO during prosecution of the applications leading to the issuance of the ’814 Patent or applications related thereto, because of disclosures or language in the specification of the ’814 Patent, and/or because of limitations in the claims of the ’814 Patent.

SEVENTH DEFENSE
(Limitations on Recovery)

109. Natera’s claims for damages and other remedies are limited by 35 U.S.C. §§ 286 and/or 288. Natera is barred by 35 U.S.C. § 288 from recovering costs associated with this action.

EIGHTH DEFENSE
(Barring of Claims for Injunctive Relief)

110. Natera is not entitled to injunctive relief against ArcherDX because any alleged injury is not immediate or irreparable, Natera has an adequate remedy at law for its alleged injury, the balance of hardships does not favor an injunction, and the public interest would be disserved by an injunction. For example, enjoining ArcherDX would have significant negative

impacts on public health and welfare, and would disrupt important medical research. Indeed, ArcherDX's products have the potential to significantly advance cancer care.

NINTH DEFENSE
(License and/or Exhaustion)

111. To the extent that any of the allegedly infringing activities is directly or indirectly related to or based on products made, sold, or provided by, or services conducted by an entity that has an express or implied license to the '814 Patent, or to the extent that any of the allegedly infringing conduct is directly or indirectly subject to rights granted to ArcherDX or another entity, Natera's claims are barred, in whole or in part, in view of such licensed rights, implied or otherwise, covenant not to sue, and/or under the doctrine of patent exhaustion.

TENTH DEFENSE
(No Standing)

112. To the extent Natera does not have title to the '814 Patent, Natera has no standing to maintain its claims.

ELEVENTH DEFENSE
(Actions of Others)

113. On information and belief, Natera's claims are barred, in whole or in part, because ArcherDX is not liable for the acts of others over whom it has no control.

TWELFTH DEFENSE
(No Exceptional Case)

114. Natera cannot prove that this is an exceptional case that justifies an award of attorney fees against ArcherDX pursuant to 35 U.S.C. § 285.

THIRTEENTH DEFENSE
(Unclean Hands)

115. Natera's patent infringement claims are barred in whole or in part under the doctrine of unclean hands.

116. As particularized below, the '814 Patent is the result of protracted and convoluted prosecution at the USPTO spanning more than a decade, and involving 16 provisional patent applications and 10 continuation or continuation-in-part applications, almost half of which were abandoned.

117. The '814 Patent is a continuation of U.S. Patent App. No. 16/140,298 filed September 24, 2018.

118. U.S. Patent App. No. 16/140,298 is a continuation of U.S. Patent App. No. 14/918,544, filed October 20, 2015.

119. U.S. Patent App. No. 14/918,544 is a continuation-in-part of U.S. Patent App. No. 14/877,925, filed October 7, 2015, which is now abandoned; a continuation-in-part of U.S. Patent App. No. 14/692,703, filed April 21, 2015; and a continuation-in-part of U.S. Patent App. No. 14/538,982. U.S. Patent App. No. 14/918,544 claims priority to U.S. Provisional App. No. 62/147,377, filed April 14, 2015; U.S. Provisional App. No. 62/146,188, filed April 10, 2015; and U.S. Provisional App. No. 62/066,514, filed October 21, 2014.

120. U.S. Patent App. No. 14/877,925 is a continuation-in-part of U.S. Patent App. No. 14/255,356, filed March 25, 2014, which is now abandoned after the applicant failed to respond to any office action in prosecution; a continuation-in-part of U.S. Patent App. No. 13/780,022, filed February 28, 2013, which is now abandoned; and a continuation of U.S. Patent App. No. 13/683,604, filed November 21, 2012, which is now abandoned.

121. U.S. Patent App. No. 14/692,703 claims priority to U.S. Provisional App. No. 62/148,173, filed April 15, 2015; U.S. Provisional App. No. 62/147,377, filed April 14, 2015; U.S. Provisional App. No. 62/146,188, filed April 10, 2015; U.S. Provisional App. No. 62/066,514, filed October 21, 2014; U.S. Provisional App. No. 61/994,791, filed May 16, 2014;

U.S. Provisional App. No. 61/987,407, filed May 1, 2014; and U.S. Provisional App. No. 61/982,245, filed April 21, 2014.

122. U.S. Patent App. No. 14/538,982 claims priority to U.S. Provisional App. No. 62/066,514, filed October 21, 2014; U.S. Provisional App. No. 61/994,791, filed May 16, 2014; U.S. Provisional App No. 61/987,407, filed May 1, 2014; and U.S. Provisional App. No. 61/982,245, filed April 21, 2014.

123. U.S. Patent App. No. 14/255,356 is a continuation of PCT Application PCT/US2012/58578, filed October 3, 2012.

124. U.S. Patent App. No. 13/780,022 is a continuation-in-part of U.S. Patent App. No. 13/683,604, filed November 21, 2012, which is now abandoned; a continuation-in-part of PCT Application No. PCT/US2012/58578, filed October 3, 2012; a continuation-in-part of U.S. App. No. 13/335,043, filed December 22, 2011; a continuation-in-part of U.S. Patent App. No. 13/300,235, filed November 18, 2011; and a continuation-in-part of U.S. App. No. 13/110,685, filed May 18, 2011; and claims priority to U.S. Provisional App. No. 61/634,431, filed February 29, 2012.

125. U.S. Patent App. No. 13/683,604 is a continuation-in-part of U.S. Patent App. No. 13/300,235, filed November 18, 2011; a continuation-in-part of U.S. App. No. 13/110,685, filed May 18, 2011; and claims priority to U.S. Provisional App. No. 61/675,020, filed July 24, 2012.

126. PCT Application PCT/US2012/58578 is a continuation-in-part of U.S. Patent App. No. 13/300,235, filed November 18, 2011; and claims priority to U.S. Provisional App. No. 61/683,331, filed August 15, 2012; and U.S. Provisional App. No. 61/542,508, filed October 3, 2011.

127. U.S. Patent App. No. 13/335,043 is a continuation-in-part of U.S. Patent App. No. 13/300,325, filed November 18, 2011; a continuation-in-part of U.S. Patent App. No. 13/110,685, filed May 18, 2011; and claims priority to U.S. Provisional App. No. 61/426,208, filed December 22, 2010.

128. U.S. Patent App. No. 13/300,235 is a continuation-in-part of U.S. Patent App. No. 13/110,685, filed May 18, 2011; and claims priority to U.S. Provisional App. No. 61/542,508, filed October 3, 2011; and U.S. Provisional App. No. 61/571,248, filed June 23, 2011.

129. U.S. Patent App. No. 13/110,685 claims priority to U.S. Provisional App. No 61/516,996, filed April 12, 2011; U.S. Provisional App. No. 61/448,547, filed March 2, 2011; U.S. Provisional App. No. 61/462,972, filed February 9, 2011; U.S. Provisional App. No. 61/398,159, filed June 21, 2010; and U.S. Provisional App. No. 61/395,850, filed May 18, 2011.

130. In connection with the above applications, Natera filed *hundreds* of proposed claims with the USPTO.

131. Prior to the filing of the ’814 Patent application on April 30, 2019, Natera had *never* disclosed nor sought claims corresponding to the claims of the ’814 Patent.

132. On information and belief, Natera drafted the claims of the ’814 Patent in an egregious attempt to cover ArcherDX’s proprietary AMP™ processes—methods of amplifying DNA that Natera did not invent.

133. Indeed, Natera filed the ’814 Patent application only after one of its senior executives left Natera, began working for ArcherDX, gained access to confidential information relating to ArcherDX’s products, including LIQUIDPlex™, STRATAFIDE™ and PCM, and then returned to Natera.

134. Moreover, on information and belief, Natera knew or should have known that the '814 Patent is invalid under at least 35 U.S.C. §§ 101 and 103 given Natera's own admissions made in court filings in this District and elsewhere, representative examples of which are set forth below in ArcherDX's Counterclaims.

135. On information and belief, Natera has improperly sought to delay competition in the IVD market by pursuing patent claims it did not invent, and subsequently prematurely asserting an invalid patent that does not cover ArcherDX's products in development.

136. Based on the foregoing business misconduct, the relief Natera seeks in this action is barred by reason of its unclean hands.

FOURTEENTH DEFENSE
(Prosecution Laches)

137. Natera's patent infringement claims are barred in whole or in part under the doctrine of prosecution laches.

138. As described above, on information and belief, Natera engaged in an unreasonable and undue delay in the prosecution of the '814 Patent, which has prejudiced ArcherDX. Thus, as a matter of equity, the '814 Patent cannot be enforced against ArcherDX.

ARCHERDX'S COUNTERCLAIMS

Defendant / Counterclaimant ArcherDX, Inc. ("ArcherDX") asserts Counterclaims against Plaintiff / Counterclaim-Defendant Natera, Inc. ("Natera") as follows:

NATURE OF ACTION

1. For its Counterclaims, ArcherDX seeks declarations that its LIQUIDPlex™ product does not infringe U.S. Patent Nos. 10,538,814 (the "'814 Patent") and that the '814 Patent is invalid.

PARTIES

2. ArcherDX is a Delaware corporation with a principal place of business at 2477 55th Street, Suite 202, Boulder, Colorado 80301.

3. On information and belief, and as alleged by Natera in its Complaint, Natera is a corporation organized and existing under the laws of the state of Delaware, with its principal place of business at 201 Industrial Road, San Carlos, California 94070.

JURISDICTION AND VENUE

4. This Court has subject matter jurisdiction over this action under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202 as to ArcherDX's counterclaims against Natera pursuant to the patent laws of the United States, Title 35, United States Code, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. An actual, substantial, and continuing justiciable controversy exists between Natera and ArcherDX based on Natera having filed a Complaint against ArcherDX alleging infringement of the '814 Patent by sales of LIQUIDPlex™ for research use only, with respect to which ArcherDX requires declaration of its rights by this Court. Specifically, the controversy concerns non-infringement and invalidity of the '814 Patent.

5. Personal jurisdiction over Natera is proper because Natera has submitted itself to the jurisdiction of this Court by, among other things, filing the Complaint.

6. To the extent venue is proper in the underlying patent infringement action, venue is proper here as to these Counterclaims under 28 U.S.C. §§ 1391(b)–(c) and 28 U.S.C. § 1400(b).

FIRST COUNTERCLAIM
(Declaratory Judgment of Non-Infringement of the '814 Patent)

7. ArcherDX realleges and incorporates its preliminary statement, and the allegations set forth in paragraphs 1-6 of these Counterclaims as if fully restated herein.

8. In its Complaint, Natera alleges that ArcherDX has infringed and continues to infringe the ’814 Patent by its sale of LIQUIDPlex™ for research use only.

9. ArcherDX has not and is not now infringing, inducing the infringement of, or contributing to the infringement of any valid and enforceable claim of the ’814 Patent by its sale of LIQUIDPlex™ for research use only.

10. For example, claim 1 of the ’814 Patent recites “performing a first PCR…using a universal primer” and “performing a second, nested PCR…using the universal primer.” ArcherDX’s LIQUIDPlex™ product does not employ “a second, nested PCR…using the universal primer” of the first PCR.

11. ArcherDX further lacked and continues to lack the requisite intent or knowledge to induce or contribute to the direct infringement of the ’814 Patent by another by its sale of LIQUIDPlex™ for research use only.

12. A justiciable controversy exists as to whether ArcherDX has infringed any valid and enforceable claim of the ’814 Patent by its sale of LIQUIDPlex™ for research use only.

13. ArcherDX is entitled to a judgment declaring that ArcherDX has not directly or indirectly infringed, either literally or under the doctrine of equivalents, any valid and enforceable claim of the ’814 Patent by its sale of LIQUIDPlex™ for research use only.

SECOND COUNTERCLAIM
(Declaratory Judgment of Invalidity of the ’814 Patent)

14. ArcherDX realleges and incorporates its preliminary statement, and the allegations set forth in paragraphs 1-13 of these Counterclaims as if fully restated herein.

15. The claims of the ’814 Patent are invalid in view of the prior art and/or for failure to comply with one or more conditions for patentability set forth under 35 U.S.C. including but not limited to §§ 101, 102, 103, and 112 *et seq*., and the rules, regulations, and laws pertaining to

those provisions, including the applicable provisions of Title 37 of the Code of Federal Regulations.

16. ArcherDX is entitled to judgment declaring that the claims of the ’814 Patent are invalid in view of the prior art and/or for failure to comply with one or more of the requirements of the United States Patent Act set out in 35 U.S.C. §§ 1, *et seq*., including without limitation 35 U.S.C. §§ 101, 102, 103, and 112.

Invalidity under 35 U.S.C. § 101

17. Accepting as true Natera’s own statements made in proceedings in this District and elsewhere, the claims of the ’814 Patent are directed to unpatentable naturally occurring subject matter, phenomena, and/or relationships, and any additional elements in the claims are merely well-understood, routine, or conventional. Thus, the claims of the ’814 Patent are unpatentable under 35 U.S.C. § 101.

18. For example, in another case pending in this District, *CareDX, Inc. et al. v. Natera, Inc.*, No. 19-cv-567 (D. Del.) (“CareDX”), Natera has alleged that the claims of the two patents-in-suit there—U.S. Patent Nos. 8,703,652 and 9,845,497—are unpatentable under 35 U.S.C. § 101. *See CareDX*, No. 19-cv-567, D.I. Nos. 9-10, 19 (Natera’s Motion to Dismiss and Briefing Related Thereto), 63 (Natera’s Objections to Report and Recommendation) (attached as Exhibits 1-4). The two patents asserted in *CareDX* claim priority to applications filed in 2009 and 2010, which is before the earliest possible priority date for the claims of the ’814 Patent.

19. Similarly, in *Illumina, Inc. v. Natera, Inc.*, No. 18-cv-01662 (N.D. Cal.) (“Illumina”), Natera has alleged that the claims of U.S. Patent No. 9,493,831 are unpatentable under Section 101. *See Illumina*, No. 18-cv-01662, D.I. Nos. 24, 35 (Motion to Dismiss and Briefing Related Thereto) (attached as Exhibits 5-6). The patent asserted in *Illumina* claims

priority to an application filed in 2010, which is before the earliest possible priority date for the claims of the '814 Patent.

20. In this case, representative claim 1 of the '814 Patent recites a "a method for amplifying and sequencing DNA" comprising (1) ligating adaptors to isolated cell-free DNA, (2) performing a first round of polymerase chain reaction (PCR), (3) performing a second, "nested" round of PCR that includes use of a sequencing tag, and (4) performing high-throughput sequencing to sequence the cell-free DNA.

21. But in *CareDX*, Natera itself acknowledged that cell-free DNA is a natural phenomenon, and alleged that amplification and sequencing methods, such as PCR and high throughput sequencing, were known and used in the art to detect and sequence cell-free DNA. *E.g.*, *CareDX*, D.I. No. 10 at 12-19; D.I. No. 19 at 6-7; D.I. No. 63 at 3-5. And in *Illumina*, Natera also argued that cell-free DNA is "naturally occurring," and the use of "well-known, routine, and conventional amplification techniques"—including nested PCR, and the use of primers with attached sequencing tags—to amplify and sequence the DNA is not patentable. *See Illumina*, No. 18-cv-01662, D.I. No. 24 at 2, 6-8; D.I. No. 35 at 2-9.

22. Thus, by Natera's own admissions, the claims of the '814 Patent are unpatentable under 35 U.S.C. § 101, and Natera should never have filed its Complaint against ArcherDX.

Invalidity under 35 U.S.C. §§ 102 and 103

23. The claims of the '814 Patent are invalid under 35 U.S.C. § 102 and/or § 103, in view of, for example, the following prior art, alone or in combination with additional prior art: Mir and Spertini or Makarov, which disclose all elements of the '814 Patent claims. Natera disclosed Mir as one of *thousands* of references during prosecution of the '814 Patent. Natera did not disclose either Spertini or Makarov to the USPTO during prosecution of the '814 Patent.

Moreover, the ’814 Patent is at least obvious under 35 U.S.C. § 103 given Natera’s own admissions made in court filings in this District and elsewhere, representative examples of which are set forth above in paragraphs 17-21.

24. The ’814 Patent is also not entitled to a priority date earlier than its filing date of April 30, 2019, because Natera’s provisional applications and earlier-filed applications do not comply with the requirements of 35 U.S.C § 112, as required by 35 U.S.C §§ 119 and 120. The provisional applications and earlier-filed applications do not contain a written description of the claims of the ’814 Patent or contain sufficient information to enable a person of ordinary skill in the art to which they pertain to practice the full scope of the claims of the ’814 Patent. Indeed, none of the provisional applications or earlier-filed applications disclosed or sought claims corresponding to the claims of the ’814 Patent, which recite processes that Natera did not invent.

Invalidity under 35 U.S.C. § 112 and Improper Inventorship

25. The claims of the ’814 Patent are invalid under 35 U.S.C. § 112.

26. The claims of the ’814 Patent lack written description support in the specification.

27. As an example, the specification of the ’814 Patent does not disclose an embodiment or example corresponding to claim 1 of the ’814 Patent and does not otherwise disclose that the named inventors of the ’814 Patent were in possession of the alleged invention recited in the claims as of the priority date of the ’814 Patent.

28. Indeed, prior to the filing of the ’814 Patent application on April 30, 2019, Natera had never disclosed nor sought claims corresponding to the claims of the ’814 Patent.

29. The specification also does not contain sufficient information to enable a person of ordinary skill in the art to which the patent pertains to practice the full scope of the claims of the ’814 Patent.

30. The ’814 Patent does not satisfy the requirements of 35 U.S.C. § 112 because the applicants for the ’814 Patent did not themselves invent the subject matter sought to be patented—an independent ground for invalidating the patent.

RESERVATION OF RIGHTS

31. ArcherDX expressly reserves the right to assert any additional defenses or counterclaims that may now exist or in the future may be available based on discovery and further factual investigation in this case.

DEMAND FOR JURY TRIAL

32. ArcherDX hereby demands a trial by jury of all issues so triable in this action.

PRAYER FOR RELIEF

33. ArcherDX respectfully requests this Court grant relief as follows:

A. Judgment that Natera’s Complaint in its entirety be dismissed with prejudice;

B. Judgment that Natera is entitled to nothing by its Complaint, including that Natera is not entitled to an award of compensatory damages, attorneys’ fees, costs, pre-judgment or post-judgment interest under 35 U.S.C. §§ 284 or 285, or any applicable law;

C. Denial of any and all of Natera’s requests for injunctive relief;

D. Judgment that ArcherDX has not infringed, and is not infringing, any valid and enforceable claim of the ’814 Patent by its sale of LIQUIDPlex™ for research use only;

E. Judgment that the claims of the ’814 Patent are invalid;

F. Judgment that Natera and/or any of its successors and attorneys, and all persons in active concert or participation with any of them, are enjoined from directly or indirectly asserting infringement or instituting any further action for infringement of the '814 Patent against ArcherDX, or any of ArcherDX's customers, end-users, agents, suppliers, contractors, consultants, successors, and assigns;

G. Order that this case is "exceptional" pursuant to 35 U.S.C. § 285 entitling ArcherDX to an award of its reasonable and necessary attorneys' fees, expenses, and costs, and prejudgment interest thereon;

H. Order awarding ArcherDX its costs incurred in this action; and

I. Grant to ArcherDX such other and further relief as the Court deems just and proper.

Respectfully submitted,

DATED: March 25, 2020

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